NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE

DRAFT

PROFICIENCY TESTING PROGRAM

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2.0 PROFICIENCY TESTING PROGRAM

Proficiency Testing (PT) is an external means of evaluating a laboratory's performance against a given set of criteria using unknown samples under controlled conditions. PT is one of several essential elements of the overall NELAP accreditation process. It is not the sole criterion for determining accreditation status.

2.0.1 Expectations

The PT program will evaluate laboratories' ability to generate data of comparable and known quality that is sufficient to meet program requirements. As a result of the PT program, laboratory performance is expected to improve over time.

2.0.2 Practical Goals

The PT program incorporates several practical goals: It should be technically defensible. It must be affordable for all participants. The PT samples themselves should thoroughly challenge the analytical procedures. They should resemble real world matrices, with concentrations that reasonably represent applicable environmental program requirements.

2.0.3 Scope

The PT program is intended to cover all types of environmental analyses. However, the body of the PT standard applies primarily to chemistry. Appendices (yet to be developed) will describe necessary variations as applied to radiochemistry, biology, and microbiology.

2.1 ROLES AND RESPONSIBILITIES

The PT program structure incorporates five major participant groups, each with distinctive roles and responsibilities. These include the standard-setting authority, the oversight body, the PT study providers, the laboratories, and the accrediting authorities.

2.1.1 Standard-setting Authority

EPA's NELAP is the standard-setting authority. EPA established NELAC to develop the standard and to keep it current. The standard-setting authority determines PT fields of testing, parameters, concentration ranges, and any applicable method detection limits.

2.1.2 Oversight Body

The oversight body establishes and implements procedures to assure that the providers meet the PT program criteria. The oversight body also maintains a database of PT results and performance.

2.1.3 Providers

The providers produce and distribute PT samples, evaluate study results against published criteria, and report the results to the laboratory, the respective accrediting authority, the oversight body, and NELAP.

2.1.4 Laboratories

The laboratories participate in PT studies as required by the NELAP standard.

2.1.5 Accrediting Authorities

The states are the accrediting authorities for those laboratories located within their respective boundaries or for laboratories seeking to do business within their boundaries. EPA is the accrediting authority for the state laboratories. The accrediting authorities make all decisions regarding a laboratory's accreditation status. They are responsible for taking action to make these determinations.

2.2 LABORATORY ENROLLMENT IN PROFICIENCY TESTING PROGRAM(S)

2.2.1 Fields of Testing

The PT program is organized by field of testing. Laboratories may choose to participate in one or more field of testing, or portions thereof. The following elements collectively define fields of testing:

(a) Regulatory or environmental program (e.g., Safe Drinking Water Act);

(b) Analyte/method suites (e.g., regulated volatiles); and

© Samples matrix types (e.g., soil, waste oil, water).

2.2.2 Required Level of Participation

In order to be accredited initially, and to maintain accreditation, each laboratory must enroll in a NELAP-approved PT program. Laboratories may request accreditation for a portion of a field of testing or for the entire field of testing. Each laboratory will participate in two PT studies per year. Each study will require the analysis of one test sample for each field of testing. This section provides the time that a laboratory has to analyze the PT samples and report the results. Data and laboratory evaluation criteria are discussed in Sections 2.5 and 2.6.

2.2.3 Requesting Accreditation

At the time it applies for accreditation, each laboratory shall notify its primary accrediting authority which field of testing, or portion thereof, that it chooses to participate in to meet PT requirements. For those tests for which PT samples are not available, the laboratory must assure the reliability of its testing procedures by maintaining a total quality management system that meets the applicable NELAP requirements.

2.2.4 Reporting Results

Laboratories seeking accreditation may select any provider from the list of NELAP-approved PT study providers. The laboratories will bear the cost of any PT study subscription. Each laboratory must authorize the PT study provider to report its results and acceptance status directly to the appropriate primary accrediting authority, NELAP, and the oversight body, as well as to the lab itself.

2.3 REQUIREMENTS FOR LABORATORY TESTING OF PT SAMPLES

A laboratory must participate in two NELAP-approved single-blind, single-sample PT studies per year for each field of

testing (or portion thereof) for which it seeks or wants to maintain accreditation. The samples must be analyzed and the results returned to the PT study provider no later than 30 calendar days from the date of sample receipt. The laboratory's management and all analysts should assure that all PT samples are handled in the same manner as real environmental samples, using the same staff, procedures, equipment, facilities and frequency of analysis.

2.3.1 Restrictions on Exchanging Information

Laboratories must comply with the following restrictions on the transfer of PT samples and communication of PT sample results:

(a) A laboratory may not send any PT sample or a portion of a PT sample to another laboratory for any analysis for which it seeks accreditation;

(b) A laboratory may not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis which the sending laboratory seeks accreditation;

© Laboratory policy shall not allow management or staff to communicate with any individual at another laboratory (even intra-company) concerning the PT sample results until after the closing date of the relevant study; and

(d) Laboratory management and staff may not attempt to obtain the target value of any PT sample from the program provider until after the closing date of the relevant study.

2.3.1.1 Consequences of Unauthorized Communication

Any laboratory that the accrediting authority or NELAP determines intentionally referred any PT sample to another laboratory for analysis before the closing date of the study becomes subject to having its accreditation revoked for a minimum period of one year. Any laboratory that knowingly receives any PT sample from another laboratory for testing before the closing date of the study must immediately notify its primary accrediting authority of the receipt of those samples. Laboratories not doing so may also have their accreditation revoked for a minimum period of one year. This policy is not intended to prevent interlaboratory

testing designed as part of a methods development or evaluation study, and only applies to PT samples used for NELAC accreditation purposes.

2.3.2 Maintenance of Records

The laboratory shall maintain for five years a copy of all written, printed, and electronic records, including but not limited to bench sheets, instrument strip charts or printouts, data calculations, and data reports, resulting from the analysis of any PT sample. These records shall include a copy of the PT study report forms used by the laboratory to record PT results, and a written document signed by the laboratory management and analysts stating that the PT samples were tested in the same manner as routine samples. All of these laboratory records shall be made available to the NELAP audit staff during on-site audits of the laboratory.

2.4 REQUIREMENTS FOR PT PROVIDERS AND STUDIES

This Section and the associated Appendix A *(reserved)* provide the criteria which all PT study providers will meet in order to be approved by NELAP or its designated PT oversight body. While rigorous and demanding, it is anticipated that several governmental and private sector organizations will meet NELAP acceptance criteria and become approved. NELAP program criteria and ongoing oversight will assure that the performance of all laboratories will be evaluated in an effective, fair, and consistent manner.

2.4.1 NELAP Lists

NELAP will maintain a list of approved PT providers. This list will be continually updated and published at intervals not to exceed six months. On this same interval, NELAP or its designee will also publish the list of analyte/method suites necessary to satisfy the PT requirements in a given field of testing for each regulatory program.

2.4.2 On-site Audit of PT Providers

The NELAP-designated PT provider oversight body will conduct an annual on-site audit of any PT provider seeking NELAP approval. The audit will evaluate and confirm that the PT provider has met the requirements described in Appendix A. The audit report and associated PT provider supplied written

documentation will be forwarded to NELAP or its designated oversight body. Approval of a PT study provider will be the responsibility of NELAP or its designated oversight body. Each applicant offering PT studies must provide written documentation of the study samples as required in Appendix B (*reserved*).

2.4.3 Provider Requirements

PT study providers will be approved on a field-of-testing basis. In order for a provider to have a PT program approved by NELAP for a field of testing, it must meet the requirements contained in Appendices A and B.

2.4.4 Sample Requirements

The matrix of all PT samples must reasonably resemble the matrices for which the laboratory seeks accreditation. Samples may not be reused.

2.4.4.1 Sample Analytes

The target concentration of each analyte in each lot of PT samples must be unique. The required group of analytes in each sample covering each field of testing is determined by NELAP or its designee and is updated annually as required. For a given field of testing, it is not necessary that every analyte be present in every study. Within each study, a certain minimum number of analytes must be present. The group of analytes included will change over time so that all are eventually included over a series of sequential studies.

2.4.4.2 Provider Sample Testing

The samples must be designed, manufactured and tested by the PT study provider for homogeneity, stability and verification of target values as required in Appendix B. This testing must verify that the quality of all samples is appropriate for use in each field of testing PT study.

2.4.5 Study Data Points

The PT study provider must have enough participants to result in 20 valid data points for each analyte in each study. However, NELAP may wave this requirement for analytes which are analyzed infrequently by the laboratory community.

2.4.6 Data Acceptance Criteria

All providers shall use the data acceptance criteria established by NELAP to evaluate laboratories' PT data. In this way, all laboratories' performance will be judged fairly and consistently.

2.4.7 Report Generation

Each PT study provider must demonstrate that it can receive and evaluate the data and issue a report within 21 calendar days of the close of each study.

2.4.8 Provider Ethics

Each PT study provider must certify that it is free of any organizational conflict-of-interest. A PT sample producer will never split a sample lot and offer these same samples for sale as known-value check samples before the unknown samples are used in a PT study. In addition, each provider must demonstrate that its security procedures are adequate to maintain confidentiality of all target values through the closing date of each study. All records must be retained for a period of five years.

2.4.9 Final NELAP Approval

Final NELAP approval is contingent on the PT study provider demonstrating that it has adequate policies and procedures to: 1) assure freedom from organizational conflict-of-interest; and 2) maintain absolute confidentiality and security of all target values through the close of each study. In addition, the PT study provider must demonstrate that the design and operation of each PT field of testing for which it seeks approval meets NELAC requirements.

2.4.10 Disapproval of PT Providers

While approval is granted on an annual basis, a PT study provider will be disapproved if documented deviations from the standard identified by the accrediting authority, the oversight body, NELAP, or participating laboratories are not resolved within 30 calendar days after the provider is notified in writing of the problem.

2.5 EVALUATION OF PROFICIENCY TESTING RESULTS

The criteria presented in this section are considered to be NELAP defaults which would apply in the absence of specific criteria established by the appropriate EPA program offices. The various EPA program offices may choose to establish their own program-specific criteria.

2.5.1 Scoring of Laboratory PT Study Results

PT study providers shall evaluate results from all PT studies using NELAP-mandated acceptance criteria as described in Appendix C (*reserved*). NELAP or its designee shall provide (and update on an annual basis) the data acceptance criteria which all PT study providers shall use for all PT studies' data. Each result will be scored on a pass-fail basis. The PT study provider will provide the participant laboratories, the accrediting authority, the oversight body, and NELAP, a report showing at least the target value, study mean, acceptance range and the pass-fail status for each analyte for each laboratory participant. The providers shall not disclose specific laboratory results or evaluations to unauthorized parties.

2.6 PT CRITERIA FOR LABORATORY ACCREDITATION

The criteria presented in this section are considered to be NELAP defaults which would apply in the absence of specific criteria established by the appropriate EPA program offices. The various EPA program offices may choose to establish their own program-specific criteria.

2.6.1 Accreditation Categories

The criteria described in this section apply individually to each field of testing or portion thereof, as defined by the laboratory seeking accreditation in its accreditation request. These criteria apply only to the PT portion of the overall accreditation standard, and the accrediting authority will consider PT results along with the other elements of the NELAC standard when determining a laboratory’s accreditation status. The accrediting authority ultimately makes all decisions regarding the accreditation status of the laboratory. There are two PT accreditation categories: “acceptable” and “not acceptable.”

2.6.2 Initial and Continuing Accreditation

When a laboratory first requests accreditation, it must successfully complete two PT studies for each requested field of testing. (Successful performance is described in Appendix C.) Once a laboratory has been granted accreditation status, it must continue to complete PT studies and maintain a history of at least two successful studies out of the most recent three. In both cases, successive studies must be completed at least 30 days apart but no more than six months apart. Failure to meet the semiannual schedule is regarded as a failed study.

2.6.3 Supplemental Studies

A laboratory may elect to conduct PT studies more frequently than required by the semiannual schedule. This may be desirable, for example, when a lab first applies for certification or when a lab fails a study and wishes to quickly reestablish its history of successful performance. These additional studies are not distinguished from the routinely scheduled studies; that is, they are counted and scored the same way.

2.6.4 Failed Studies and Corrective Action

Whenever a laboratory fails a study, it must determine the cause for the failure and take any necessary corrective action. It must then document in its own records, both the investigation and the action taken. If a laboratory fails two out of the three most recent studies, its performance is considered unacceptable under the NELAC PT Standard and the lab is subject to loss of accreditation, at the discretion of the accrediting authority.

2.6.5 Second Failed Study

The PT provider reports laboratory PT performance results to the accrediting authority at the same time that it reports the results to the laboratory. If a laboratory fails a second study, as described above, the accrediting authority

should take action within 60 days to determine the capability of the lab to meet accreditation requirements.

2.6.6 Reapplication after Second Failed Study

If a laboratory loses its accreditation and it chooses to reenter the program, it must identify and correct its performance problems within 20 days of notification of the second failure. It must collect internal QC data to verify that the problem has been corrected. Within 45 days of the second failed study, it must submit to the accrediting authority documentation of the corrective action taken and data to demonstrate that the action has been effective. It must then reapply and meet the criteria for initial accreditation.